

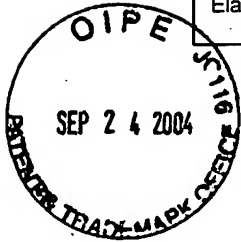
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Elaine C. Stracker



PATENT

Attorney's Docket No.: 00033.03CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Rabinowitz et al.  
Serial No.: 10/766,634  
Filed: 1/27/2004  
Title DELIVERY OF DIPHENHYDRAMINE THROUGH AN INHALATION ROUTE

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

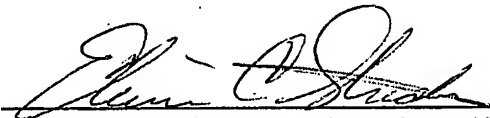
In accordance with their continuing duty of disclosure under 37 CFR §§ 1.97, 1.98 and 1.56, Applicants hereby submit for consideration in the above-identified application the enclosed references. The Information Disclosure statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

For the convenience of the Examiner, the references are listed on a PTO Form 1449 (attached) and copies thereof are enclosed. Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including any extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 502731**. Please direct all correspondence to the following customer number.

Respectfully submitted,

Date: SEP. 24 2004

  
Elaine C. Stracker J.D., Ph.D., Reg. 43,166

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/766,634	
	Filing Date	1/27/2004	
	First Named Inventor	Joshua D. Rabinowitz	
	Art Unit	Not yet known	
	Examiner Name	To be assigned	
Total Number of Pages in This Submission		Attorney Docket Number	00033.03CON

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment / Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence	<input type="checkbox"/> Status Letter
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Individual name	ALEXZA MDC, 1001 East Meadow Circle, Palo Alto, CA 94303 Elaine C. Stracker, Ph.D., J.D. Telephone (650)-687-3905	Customer Number 37485
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Date	SEP. 24 2004	

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Form PTO-1449

Docket Number: 00033.03 CON

Application Number: 10/766,634

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Applicant: Joshua D. RABINOWITZ et al.

Filing Date: 1/27/2004

Group Art Unit: Not Yet Known

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	02/02/1971	3,560,607	Hartley, et al.			
	2.	05/27/1980	Re. 30,285	Babington			
	3.	01/23/1990	4,895,719	Radhakrishnun et al.			
	4.	09/17/1991	5,049,389	Radhakrishnun			
	5.	03/31/1992	5,099,861	Clearman et al.			
	6.	02/14/1995	5,388,574	Ingebretsen			
	7.	10/03/1995	5,455,043	Fischel-Ghodsian			
	8.	10/10/1995	5,457,100	Daniel			
	9.	08/13/1996	5,544,646	Lloyd et al.			
	10.	12/09/1997	5,694,919	Rubsamen et al.			
	11.	04/07/1998	5,735,263	Rubsamen et al.			
	12.	04/14/1998	5,738,865	Baichwal et al.			
	13.	06/02/1998	5,758,637	Ivri et al.			
	14.	06/29/1999	5,915,378	Lloyd et al.			
	15.	08/10/1999	5,934,272	Lloyd et al.			
	16.	09/28/1999	5,957,124	Lloyd et al.			
	17.	10/05/1999	5,960,792	Lloyd et al.			
	18.	11/30/1999	5,993,805	Sutton et al.			
	19.	03/28/2000	6,041,777	Faithfull et al.			
	20.	04/18/2000	6,051,566	Bianco			
	21.	08/01/2000	6,095,153	Kessler et al.			
	22.	08/15/2000	6,102,036	Slutsky et al.			
	23.	10/17/2000	6,133,327	Kimura et al.			
	24.	06/05/2001	6,241,969	Saidi et al.			

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<b>Form PTO-1449</b>  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> <i>(Use several sheets if necessary)</i>	Docket Number: 00033.03 CON		Application Number: 10/766,634	
	Applicant: Joshua D. RABINOWITZ et al.			
	Filing Date: 1/27/2004		Group Art Unit: Not Yet Known	

	25.	07/03/2001	6,255,334	Sands			
	26.	01/14/2003	6,506,762	Horvath et al.			
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	31.	05/16/2002	US 2002/0058009	Bartus et al.			
	32.	07/04/2002	US 2002/0086852	Cantor			
	33.	08/22/2002	US 2002/0112723	Schuster et al.			
	34.	11/28/2002	US 2002/0176841	Barker et al.			
	35.	01/02/2003	US 2003/0004142	Prior et al.			
	36.	02/13/2003	US 2003/0032638	Kim et al.			

**RELATED ALEXZA MOLECULAR DELIVERY CORPORATION PATENT DOCUMENTS**

	37.	08/04/2003	10/633,876	Hale et al.			
	38.	08/04/2003	10/633,877	Hale et al.			
	39.	12/30/2003	10/749,537	Rabinowitz et al.			
	40.	12/30/2003	10/749,539	Rabinowitz et al.			
	41.	01/27/2004	10/766,149	Rabinowitz et al.			
	42.	01/27/2004	10/766,279	Rabinowitz et al.			
	43.	01/27/2004	10/766,566	Rabinowitz et al.			
	44.	01/27/2004	10/766,574	Rabinowitz et al.			
	45.	01/27/2004	10/766,647	Rabinowitz et al.			
	46.	01/28/2004	10/767,115	Rabinowitz et al.			
	47.	01/29/2004	10/768,205	Rabinowitz et al.			
	48.	01/29/2004	10/768,220	Rabinowitz et al.			
	49.	01/29/2004	10/768,281	Rabinowitz et al.			
	50.	01/29/2004	10/768,293	Rabinowitz et al.			

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Application Number: 10/766,634

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(Use several sheets if necessary)

Applicant: Joshua D. RABINOWITZ et al.

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Group Art Unit: Not Yet Known

	51.	01/30/2004	10/769,046	Rabinowitz et al.			
	52.	01/30/2004	10/769,051	Rabinowitz et al.			
	53.	01/29/2004	10/769,157	Rabinowitz et al.			
	54.	01/29/2004	10/769,197	Rabinowitz et al.			
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	57.	03/03/2004	10/791,915	Hale et al.			
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	63.	03/31/2004	10/813,721	Rabinowitz et al.			
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	72.	01/23/2003	US 2003/0015196	Hodges et al.			
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	75.	01/02/2003	US 2003/0000518	Rabinowitz et al.			
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	78.	01/09/2003	US 2003/0007933	Rabinowitz et al.			
	79.	01/09/2003	US 2003/0007934	Rabinowitz et al.			

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	80.	01/16/2003	US 2003/0012737	Rabinowitz et al.			
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	85.	01/23/2003	US 2003/0017114	Rabinowitz et al.			
	86.	01/23/2003	US 2003/0017115	Rabinowitz et al.			
	87.	01/23/2003	US 2003/0017116	Rabinowitz et al.			
	88.	01/23/2003	US 2003/0017117	Rabinowitz et al.			
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	96.	05/15/2003	US 2003/0091511	Rabinowitz et al.			
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	98.	07/31/2003	US 2003/0138382	Rabinowitz			
	99.	11/06/2003	US 2003/0206869	Rabinowitz et al.			
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	107.	07/01/2004	US 2004/0126328	Rabinowitz et al.			
	108.	07/01/2004	US 2004/0126329	Rabinowitz et al.			

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# INFORMATION DISCLOSURE CITATION IN AN APPLICATION

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Applicant: Joshua D. RABINOWITZ et al.

Filing Date: 1/27/2004

Group Art Unit: Not Yet Known

	109.	07/01/2004	US 2004/0127481	Rabinowitz et al.			
	110.	07/01/2004	US 2004/0127490	Rabinowitz et al.			
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Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation	
							YES	NO
	115.	03/14/1990	EP 0 358 114	Europe				
	116.	03/07/2001	EP 1 080 720	Europe				
	117.	08/29/2001	EP 0 606 486	Europe				
	118.	04/11/1996	WO 96/09846	WIPO				
	119.	05/09/1996	WO 96/13161	WIPO				
	120.	05/09/1996	WO 96/13290	WIPO				
	121.	05/09/1996	WO 96/13291	WIPO				
	122.	05/09/1996	WO 96/13292	WIPO				
	123.	10/03/1996	WO 96/30068	WIPO				
	124.	08/07/1997	WO 97/27804	WIPO				
	125.	05/28/1998	WO 98/22170	WIPO				
	126.	07/23/1998	WO 98/31346	WIPO				
	127.	08/27/1998	WO 98/36651	WIPO				
	128.	04/08/1999	WO 99/16419	WIPO				
	129.	12/16/1999	WO 99/64094	WIPO				
	130.	01/06/2000	WO 00/00176	WIPO				
	131.	01/06/2000	WO 00/00215	WIPO				

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	Applicant: Joshua D. RABINOWITZ et al.			
	Filing Date: 1/27/2004		Group Art Unit: Not Yet Known	

	132.	05/18/2000	WO 00/27363	WIPO			
	133.	05/25/2000	WO 00/29053	WIPO			
	134.	09/17/2000	WO 00/47203	WIPO			
	135.	11/02/2000	WO 00/64940	WIPO			
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	139.	01/25/2001	WO 01/05459	WIPO			
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	141.	Bennett, R.L. et al. (1981). "Patient-Controlled Analgesia: A New Concept of Postoperative Pain Relief," <i>Annual Surg.</i> 195(6):700-705.
	142.	Carroll, M.E. et al. (1990), "Cocaine-base smoking in rhesus monkeys: reinforcing and physiological effects," <i>Psychopharmacology</i> (Berl). 102:443-450.
	143.	Clark, A. and Byron, P. (1986). "Dependence of Pulmonary Absorption Kinetics on Aerosol Particle Size," <i>Z. Erkrank.</i> 166:13-24.
	144.	Darquenne, C. et al. (1997). "Aerosol Dispersion in Human Lung: Comparison Between Numerical Simulations and Experiments for Bolus Tests," <i>American Physiological Society.</i> 966-974.
	145.	Davies, C.N. et al. (May 1972). "Breathing of Half-Micron Aerosols," <i>Journal of Applied Physiology.</i> 32(5):591-600.
	146.	Dershwitz, M., M.D., et al. (September 2000). "Pharmacokinetics and Pharmacodynamics of Inhaled versus Intravenous Morphine in Healthy Volunteers," <i>Anesthesiology.</i> 93(3): 619-628.
	147.	Finlay, W.H. (2001). "The Mechanics of Inhaled Pharmaceutical Aerosols", Academic Press: San Diego Formula 2.39. pp.3-14 (Table of Contents). pp. v-viii.
	148.	Gonda, I. (1991). "Particle Deposition in the Human Respiratory Tract," Chapter 176, <u>The Lung: Scientific Foundations</u> . Crystal R.G. and West, J.B. (eds.), Raven Publishers, New York. pp. 2289-2294.

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PTO/SB/ 08 (2-92)         Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE	

Form PTO-1449

Docket Number: 00033.03 CON

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Applicant: Joshua D. RABINOWITZ et al.

Filing Date: 1/27/2004

Group Art Unit: Not Yet Known

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| 149. | Hatsukami D, et al. (May 1990) "A method for delivery of precise doses of smoked cocaine-base to humans." <i>Pharmacology Biochemistry &amp; Behavior</i> . 36(1):1-7.   |
| 150. | Heyder, J. et al. (1986). "Deposition of Particles in the Human Respiratory Tract in the Size Range 0.005-15 $\mu\text{m}$ ," <i>J. Aerosol Sci.</i> 17(5):811-822.  |
| 151. | Huizer, H., "Analytical studies on illicit heron. V. Efficacy of volatilization during heroin smoking." <i>Pharmaceutisch Weekblad Scientific Edition</i> (1987). 9(4):203-211.                                    |
| 152. | Hurt, R.D., MD and Robertson, C.R., PhD, (October 1998). "Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial," <i>JAMA</i> 280(13):1173-1181.                      |
| 153. | Lichtman, A.H. et al. (1996). "Inhalation Exposure to Volatilized Opioids Produces Antinociception in Mice," <i>Journal of Pharmacology and Experimental Therapeutics</i> . 279(1):69-76.                          |
| 154. | Martin, B.R. and Lue, L.P. (May/June 1989). "Pyrolysis and Volatilization of Cocaine," <i>Journal of Analytical Toxicology</i> 13:158-162.   |
| 155. | Mattox, A.J. and Carroll, M.E., (1996). "Smoked heroin self-administration in rhesus monkeys," <i>Psychopharmacology</i> , 125:195-201.  |
| 156. | Meng, Y. et al. "Inhalation Studies With Drugs of Abuse," <i>NIDA Research Monograph</i> , (1997) 173:201-224.   |
| 157. | Meng, Y., et al. (1999). "Pharmacological effects of methamphetamine and other stimulants via inhalation exposure," <i>Drug and Alcohol Dependence</i> . 53:111-120.   |
| 158. | Office Action mailed 8/13/2003 for US application 10/153,313 filed 05/21/2002 "DELIVERY OF BENZODIAZEPINES THROUGH AN INHALATION ROUTE"  |
| 159. | Pankow, J.F. et al. (1997). "Conversion of Nicotine in Tobacco Smoke to Its Volatile and Available Free-Base Form Through the Action of Gaseous Ammonia," <i>Environ. Sci. Technol.</i> 31:2428-2433.              |
| 160. | Pankow, J. (March 2000). ACS Conference-San Francisco-3/26/00. Chemistry of Tobacco Smoke. pp. 1-8.  |
| 161. | Seeman, J. et al. (1999). "The Form of Nicotine in Tobacco. Thermal Transfer of Nicotine and Nicotine Acid Salts to Nicotine in the Gas Phase," <i>J. Agric. Food Chem.</i> 47(12):5133-5145.                      |
| 162. | Sekine, H. and Nakahara, Y. (1987). "Abuse of Smoking Methamphetamine Mixed with Tobacco: 1. Inhalation Efficiency and Pyrolysis Products of Methamphetamine," <i>Journal of Forensic Science</i> 32(5):1271-1280. |
| 163. | Vapotronics, Inc. (1998) located at <a href="http://www.vapotronics.com.au/banner.htm">http://www.vapotronics.com.au/banner.htm</a> , 11 pages, (visited on June 5, 2000).   |
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Group Art Unit: Not Yet Known

165.

Wood, R.W. et al. (1996). "Generation of Stable Test Atmospheres of Cocaine Base and Its Pyrolyzate, Methylecgonidine, and Demonstration of Their Biological Activity." *Pharmacology Biochemistry & Behavior*. 55(2):237-248.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.